To Aid Patient-Prosthesis Matching
- First determine patient’s body surface area (BSA).
- Second, using the chart, select a valve size with iEOA > 0.85 to avoid moderate PPM.

**Evolut™ Hemodynamic Reference Values**

<table>
<thead>
<tr>
<th>Annular Diameter (mm)</th>
<th>≤ 22.3</th>
<th>&gt; 22.3 to ≤ 23.2</th>
<th>&gt; 23.2 to ≤ 24.7</th>
<th>&gt; 24.7 to ≤ 26.2</th>
<th>&gt; 26.2 to ≤ 30.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter Derived Annular Area (mm²)</td>
<td>≤ 391</td>
<td>391-423</td>
<td>423-479</td>
<td>479-539</td>
<td>539-716</td>
</tr>
<tr>
<td>EOA Ref Data (cm²)</td>
<td>1.66 ± 0.42 (n = 53)</td>
<td>1.82 ± 0.43 (n = 38)</td>
<td>1.98 ± 0.56 (n = 62)</td>
<td>1.98 ± 0.59 (n = 49)</td>
<td>2.56 ± 0.77 (n = 53)</td>
</tr>
</tbody>
</table>

**Sapien™ 3 Hemodynamic Reference Values**

<table>
<thead>
<tr>
<th>Annular Area (mm²)</th>
<th>≤ 22.1</th>
<th>&gt; 22.2 to ≤ 23.64</th>
<th>&gt; 23.64 to ≤ 24.9</th>
<th>&gt; 24.9 to ≤ 26.2</th>
<th>&gt; 26.2 to ≤ 29.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>EOA Ref Data (cm²)</td>
<td>1.41 ± 0.27 (n = 189)</td>
<td>1.58 ± 0.33 (n = 191)</td>
<td>1.73 ± 0.36 (n = 192)</td>
<td>1.79 ± 0.35 (n = 191)</td>
<td>1.91 ± 0.42 (n = 188)</td>
</tr>
</tbody>
</table>

The analysis provided above assesses data from separate clinical studies. These charts are not intended to be a direct comparison of these devices as there is no head-to-head clinical study, but rather are intended to illustrate an analysis of similar trials. Multiple factors, including the use of different echo corelabs, contribute to clinical study outcomes and need to be considered in making any assessments across different studies. Where measurements are derived, conversions assume circularity.

**References**

**Indexed Effective Orifice Area (iEOA) = EOA/BSA**

- **iEOA > 0.85 cm²/m²**: mild
- **0.85-0.65 cm²/m²**: moderate
- **< 0.65 cm²/m²**: severe

**Evolut™ TAVR System**

**TAVR HEMODYNAMICS**

**WHAT YOU NEED TO KNOW**
**Evolut TAVR Platform**

**Sapien 3**

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**INDICATIONS**

The Medtronic CoreValve™ Evolut™ R and CoreValve™ Evolut™ PRO systems are indicated for use in patients with symptomatic severe aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy. The Medtronic CoreValve™ Evolut™ R or CoreValve™ Evolut™ PRO systems are indicated for use in patients with symptomatic severe aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy. When using Model EVOR-US/PRO-US-14-US or ≥ 5.5 mm when using Model EVOR-US/PRO-US-18-US, provide a 20 Fr introducer sheath. When using Model EVOR-US/PRO-US-14-US or ≥ 5.5 mm when using Model EVOR-US/PRO-US-18-US, provide a 20 Fr introducer sheath. When using Model EVOR-US/PRO-US-14-US or ≥ 5.5 mm when using Model EVOR-US/PRO-US-18-US, provide a 20 Fr introducer sheath.

**Caution:**

The technical name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO device. 

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**Avocado**

Avoid prolonged or repeated exposure to avocado. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. The Evolut TAVR Platform uses enhanced latex-free,catheters. Avoid reprocessing, or re-use these products. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the devices and/or create a risk of contamination of the devices, which could result in patient injury, illness, or death. The bioprosthesis size must be appropriate to fit the patient’s anatomy. Proper sizing of the devices is the responsibility of the physician. Refer to the Instructions for Use for available sizes. Failure to implant a device within the somatic zone could result in adverse events such as those listed below. Patients must present with transvalvular access valve diameters of 15 mm when using Model EVOR-US/PRO-US-14-US or ≥ 5.5 mm when using Model EVOR-US/PRO-US-18-US, and the access valve diameters of 18 mm when using Model EVOR-US/PRO-US-14-US or ≥ 5.5 mm when using Model EVOR-US/PRO-US-18-US.

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**SIZING COMPARISONS**

**EVOLUT™ TAV vs. SAPIEN™ 3 TAV**

Sources: Evolut-PRO FIU (M970312001 Rev. 1C), Sapien 3 FIU (10001534004 A).

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**Medtronic® 710**

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**Use:** Evolut-PRO FIU (M970312001 Rev. 1C), Sapien 3 FIU (10001534004 A).

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**Sizing conversion assumes circularity.**

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**Evolut-PRO FIU (M970312001 Rev. 1C), Sapien 3 FIU (10001534004 A).**

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Area (mm²) for reference only. For Evolut Platform sizing always refer to the IFU. Sizing conversion assumes circularity.